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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,486	11/15/2001	Han Htun	30426.1USD1	3266

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,486	HTUN ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 17* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

3. For convenience, claim 16, the sole independent claim, is reproduced below.

16. (Previously presented) A method of screening for a ligand that activates the translocation of a steroid receptor to the nucleus in a mammalian cell comprising:

a. contacting a mammalian cell having a nucleus with the ligand, wherein the cell has a plurality of steroid receptor response elements, wherein the steroid receptor response elements comprise a plurality of AGAACA (SEQ ID NO:4) or AGGTCA (SEQ ID NO:5), in an array such that the response element can be directly detected when bound by fluorescently labeled steroid receptor; and

b. detecting the location of fluorescence within the cell,

a change in the relative fluorescence of the nucleus to the cytoplasm so as to increase the fluorescence of the nucleus indicating a ligand that activates the translocation of a steroid receptor to the nucleus in a mammalian cell.

4. For purposes of examination, the claims have been interpreted as encompassing any cell (e.g., smooth, skeletal, or cardiac muscle; neuronal, osteoclast, ectodermal, stem, etc.) from any mammal (whales, monotremes, ungulates, humans, equine, bovine, porcine, rodents, etc.). In contrast, page 13 of the specification teaches:

> The present invention provides cell lines such as the murine cell line 3134, that contains a set of mouse mammary tumor virus (MMTV) Harvey murine sarcoma virus (HaMuSV) v-ras sequences organized in a head-to-tail tandem array of approximately 200 copies. Each MMTV promoter sequence in this array contains 4 glucocorticoid receptor (GR) binding sites; the complete array thus contains nearly 1000 GR binding sites. This cell is used to visualize directly the interaction between GR and its binding site in chromatin in living cells. This is accomplished with a fluorescent labeled copy of the GR.

5. It is noted with particularity that the claimed method is directed to the use of a modified cell line, not to the creation thereof. Accordingly, the specification must contain an adequate written description of the full genus of embodiments encompassed by the claims, e.g., claim 16,

especially as it relates to the availability of such critical starting materials and how they are to be used, including their best mode. Page 16 of the specification teaches *inter alia*

> The cell can be derived from any desired mammal, such as, for example, human, monkey, mouse, hamster and rat.

A review of the specification, however, fails to provide an adequate written description of such contemplated other cell lines so as to reasonably suggest that applicant was in possession of, or had even identified the full genus of suitable cells to be used n the claimed method, whether or not the cells a naturally occurring or modified through the hand of man. While the specification does provide an adequate written description for one cell line (ATCC Accession Number CRL-11998), the specification is silent as to how alternative cells are to be identified, much less used when they comprise the recited steroid response elements. This is especially significant when the cell is other than murine in origin, and which can also be highly differentiated.

Rather than provide the full, clear, concise and exact description of the invention that the statue demands, it appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

6. In view of the considerable breadth of the claims, the limited disclosure, the specification has not been found to provide an adequate written description of the full genus encompassed by the claims. In view of such issues, applicant is urged to consider moving claim 18 into claim 16. In added support of this position it is noted that in parent application 09/091,042, now US Patent 6,455,300 B1, issued 24 September 2002, only one claim was issued and then it was to the specific cell line deposited with ATCC, which is recited in claim 18 of the instant application.

7. For the above reasons and in the absence of convincing evidence to the contrary, claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Allowable Subject Matter

8. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to argument

9. Agreement is reached with applicant's representative in that the specification does contain forward-looking statements as to what "can" be done. Such forward-looking statements, however, do not rise to the level of reasonably suggesting that applicant was in possession of the full genus of embodiments encompassed by the claims.

10. At page 4, bridging to page 5, attention is directed to the identification of a specific cell line, *supra*, which the Office has identified as allowable subject matter in claim 18. Claims 16 and 17 are not so limited, and claim 18 is currently written in dependent form from rejected claim 16.

11. Argument is presented that cells from any mammal could be applied, and then asserts at page 6, last paragraph, "the ligand is RU486." A careful review of the specification fails to find how a ligand such as RU486 (a.k.a., the morning after pill) would be a useful ligand when the cells are from an egg-laying (non-placental) mammal such as found in monotremes.

12. At pages 6-7, argument is presented as to the specification as being enabling, citing the *Forman* factors. This argument has been fully considered and has not been found persuasive as the rejection under 35 USC 112, first paragraph, was based with respect to failing to provide an adequate written description of the invention, not under enablement.

13. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
15 May 2006